

Synopsis: As the Board of Health considers secure medicine return, it must decide which leftover and expired medicines will be “covered.” The definition of “covered drugs” specifies the medicines that the product stewardship program will be required to accept, collect, and safely dispose of. The definition of “covered drugs” also determines which medicine producers will be responsible for financing and providing the product stewardship program.

What’s currently included in local voluntary take-back programs:

- The DEA’s collection events accept over-the-counter medicines and prescription drugs.
- 32 of 33 programs in King County accept prescription and over-the-counter medications used in the home, including pet medications. Pills, ointments, and liquid forms of medicine are accepted.
- Some programs also accept vitamins and supplements.
- Current voluntary take-back programs typically accept leftover prescription veterinary medicines from residential sources, which range from cardiac medicines to antibiotics to narcotics for arthritis pain, because these drugs in the home can also pose a risk of poisoning for humans.
- Excluded items include sharps and epi-pens, personal care products, and devices such as thermometers, glucometers, and insulin pumps.

Other take-back programs:

- A few drugs with unique toxicity or risks have a producer sponsored take-back system approved through a FDA managed Risk Evaluation and Mitigation Strategy (REMS, 21 U.S.C. Sec. 355-1).
- Some manufacturers of biologic drugs may provide take-back options for certain drugs, such as mail-back systems.

Considerations for this decision include:

- What leftover and expired medicines need to be collected for proper disposal to protect public health and safety?
- How will take-back operations be impacted by drugs included and excluded in the BOH regulations?
- Which drugs should logically be excluded? (sunscreen, toothpaste, flea collars, etc.)
- How will drugs covered by the BOH regulation affect program convenience and consumer behavior?

Sources of drugs restricted to “residential”

- For purposes of this policy discussion focusing on leftover and expired medicines from residential sources, not from clinical or business sources.
- Further work will be needed to define “residential sources” and “covered entities” to address facilities that are challenging to classify as either residential or business sources, such as some nursing homes.

Policy decisions to be made:

1. *Should the policy include prescription drugs from residential sources, both brand name and generic, sold in any form? This includes controlled substances.*
 - Recommended exclusions are:
 - Drugs for which producers provide a take-back program as part of a FDA approved REMS plan.
 - Drugs that are biological products if the producer already provides a take-back program. This exclusion would cover biologic drugs sold by prescription, or over-the-counter (if any).

Considerations:

- Number of manufacturers making prescription drugs sold in WA State, see “Drug Companies Whose Products are Distributed in Washington State by Cardinal Health,” attached.
- Controlled substances currently can only be received by law enforcement agencies. It is possible to construct a regulation that authorizes use of current legal options for collection of controlled substances, and allows flexibility for incorporation of new legal options when they are implementable in King County.

2. *Should the policy include over-the-counter drugs from residential sources?*

- Background: The regulatory distinction between prescription and OTC drugs reflects whether the FDA deems the drug safe for self-medication when used as instructed, not whether the drug poses a risk of poisoning or abuse if accidentally or intentionally misused. See handout on “Drug Abuse and Preventable Poisonings from Over-the-Counter Medicines.” As the subcommittee looks to make a take-back program convenient and implementable, it is important to note that many consumers don’t know which drugs are prescription or OTC.
- Recommended OTC exclusions are:
 - o OTC drugs that are also regulated as cosmetics under the federal Food, Drug, and Cosmetic Act. Examples: sunscreens, moisturizers and makeup with sun protection claims, shampoos, toothpaste, acne medicines, medicated lip balm, and antiperspirants.
 - o Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms.
- Considerations:
 - o Impact on take-back operations if OTC drugs are excluded.
 - o OTC are also a source of abuse and poisoning in the home.
 - o Number of manufacturers making OTC drugs sold in WA State. Most of these companies also make prescription drugs, see “Drug Companies Whose Products are Distributed in Washington State by Cardinal Health,” attached.

3. *Should the policy exclude other products?*

- Recommended exclusions are:
 - Vitamins and supplements.
 - Herbal-based remedies and homeopathic drugs, products, or remedies.

Attachments:

- *Definitions of Drugs and Types of Drugs*
- *“What Can You Take Back?” list of items accepted at local take-back programs*
- *Drug Abuse & Preventable Poisonings from Over-the-Counter Medicines*
- *Drug Companies Whose Products are Distributed in Washington State by Cardinal Health*
- *Your Health at Hand Book: Guide to OTC Active Ingredients in the United States*
- *Policy Comparison Table: #1 “Medicines Accepted for Return (covered drugs)”*